RECORD AND BRIEFS

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No. 14-1538

IN THE

Supreme Court of the United States

LIFE TECHNOLOGIES CORPORATION; INVITROGEN IP HOLDINGS, INC.; APPLIED BIOSYSTEMS, LLC,

Petitioners,

v.

PROMEGA CORPORATION,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONERS

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INTRODUCTION

Promega does not defend the Federal Circuit's interpretation of 35 U.S.C. § 271(f)(1). Promega does not argue that the term "substantial" in the phrase "all or a substantial portion of the components of a patented invention" should be defined to mean "important." Instead, Promega asks this Court to rule that the phrase "substantial portion" can mean anything a jury decides it means. A jury can base liability for foreign sales on the amount of components supplied from the United States *or* the importance, or even the price, of any one component. Brief for Respondent ("Br.") 12. Guided only by a "wide range of factors" that include literally "any ... relevant evidence" of a component's "significance to the invention as a whole," Br. 33-34, Promega would have juries decide whether the supply of even a single commodity component like *Taq* polymerase, used for its well-known function, exposes the supplier to worldwide patent infringement damages.

What Promega has proposed is not statutory interpretation, but the abandonment of a court's role to define the meaning of a statute. There is no reason to believe Congress intended § 271(f)(1) to empower unguided juries to decide when a product that incorporates *any* U.S.-sourced component can trigger U.S. patent liability for worldwide sales. No principle of statutory interpretation supports this approach. To the contrary, strong textual and structural indications—including especially the interplay of § 271(f)(1) with § 271(f)(2)—demonstrate that the phrase "substantial portion" refers to the number, not the importance, of the components supplied.

Promega criticizes the quantitative interpretation as difficult to administer in some imagined cases.

But its own amorphous test ensures that domestic component suppliers will be unable to plan for potentially massive patent liability for foreign sales by their customers. Promega cannot deny that its extraordinarily vague and expansive test will seriously harm U.S. component manufacturers, forcing them to relocate offshore to avoid risk of liability. Nor does it deny that this result is directly contrary to Congress's intent in passing the statute.

Promega also cannot square its proposal with the presumption against extraterritoriality, which applies "with particular force in patent law." *Microsoft* v. *AT&T Corp.*, 550 U.S. 437, 454–55 (2007). So Promega tries to evade that presumption altogether, arguing it is inapplicable because supplying a single commodity component from the United States is "domestic conduct." *E.g.*, Br. 44 (capitalization omitted). But Promega ignores that the statute regulates foreign conduct by establishing liability for foreign actors who "cause[] to be supplied ... from the" U.S. a component of an invention. 35 U.S.C. § 271(f)(1). Promega also ignores all the other foreign conduct its proposal implicates—the supply of the remaining components, their assembly into the finished kits, and the sale of the kits. Promega's argument is thus irreconcilable with cases reaching back to *Brown* v. *Duchesne*, 60 U.S. (19 How.) 183 (1857), that applied the presumption to reject the extension of U.S. patent law over products manufactured and sold abroad.

Finally, Promega contends that the district court's grant of judgment as a matter of law should not be reinstated because Life Technologies supposedly conceded that two components constituted a "substantial portion" of the invention, and that two components of certain kits were supplied from the U.S. Life Technologies, however, made no such concessions. Ra-

ther, the district court correctly held that *Promega* conceded that judgment as a matter of law is appropriate unless Life Technologies supplied multiple components of all kits from the U.S. The Federal Circuit's erroneous interpretation of § 271(f)(1) should be reversed, and the district court's judgment in Life Technologies' favor under § 271(f)(1) should be reinstated.

I. PROMEGA'S INTERPRETATION IS INCONSISTENT WITH THE STATUTE'S TEXT AND STRUCTURE.

This case presents a pure question of law for this Court to resolve de novo: whether the Federal Circuit erred in interpreting the word "substantial" in § 271(f)(1) to mean "important," such that a single commodity component can be deemed "all or a substantial portion of the components" of a multi-component invention. Pet. App. 28a-29a. Promega's response is to urge this Court to abandon interpreting the statute. To Promega, this case involves a "case-specific factual finding" with "ample support in the record" that is "entitled to deference" from this Court. Br. 16. That is not how statutory interpretation works. The point is to interpret the statute so that manufacturers, judges and juries will know what conduct will expose U.S. exporters and their foreign customers to potential liability. Life Technologies and the United States have offered such an interpretation: "the phrase 'all or a substantial portion of the components' means all or something close to all of the components, rather than just one." Brief for the United States as Amicus Curiae Supporting Petitioners ("U.S. Br.") 8; Pet. Br. 3-4. Promega has not.

At Promega's urging, the Federal Circuit defined "substantial" to mean "important." Promega now

abandons that interpretation, instead defining "substantial" to mean "considerable in amount *and/or* importance." Br. 12 (emphasis added). Moreover, this "test" makes anything and everything relevant:

> the component's function relative to the patented invention; the component's economic cost and value; its novelty within the industry; the extent to which the component is featured or discussed in materials promoting the invention; whether it is necessary for the invention to function; and any other relevant evidence.

Br. 33-34. This is no test at all. It simply leaves the question for a jury to decide on an *ad hoc*, unpredictable basis. The statute's text and structure provide no support for this view.

1. Promega's interpretation impermissibly combines separate meanings of the word "substantial." When a statutory term could bear more than one meaning, the Court's role is "to resolve that ambiguity," *Robinson* v. *Shell Oil Co.*, 519 U.S. 337, 345 (1997), by making "a selection between accepted alternative meanings," *MCI Telecomms. Corp.* v. *Am. Tel. & Tel. Co.*, 512 U.S. 218, 227 (1994). Considered in isolation, the word "substantial" could mean either "essential, material," or "[o]f ample or considerable amount, quantity, or dimensions." 2 *Compact Edition of the Oxford English Dictionary* 3129 (1980). Major dictionaries—including two of the three dictionaries Promega relies upon—list the quantitative and qualitative senses as *different* definitions. *Id.*; Br. 18; see also *Webster's New Twentieth Century Dictionary* 1817 (2d ed. 1981) (same).[1] Promega's suggestion

[1] One dictionary provides a combined definition: "[c]onsiderable in importance, value, degree, amount, or extent." Br. 18

that this Court should not decide which meaning the statutory term bears as a matter of law, but instead should leave it to juries to determine in each case, is simply not statutory interpretation. Br. 12.

The ordinary tools of statutory construction clearly demonstrate that the word "substantial" in § 271(f)(1) bears a quantitative, not a qualitative, meaning. Promega does not contest that the surrounding words, including "all" and "portion," are quantitative in nature. See *Yates* v. *United States*, 135 S. Ct. 1074, 1085 (2015) (plurality). Rather, Promega argues that "the use of the disjunctive 'or' presumptively signals Congress's intent to give the two statutory terms" their "separate, normal meanings." Br. 23. But the question is what the use of the terms demonstrates about the meaning of the phrase as a whole. As the United States explains, the inclusion of "all or" shows both that the word "substantial" is being used in a quantitative sense, and that substantiality should be judged based on how close the portion of components supplied is to *all* of the components. U.S. Br. 25; see *id.* at 15. Under Promega's interpretation, the phrase "all or" is superfluous, because "the supply of 'all ... the components' necessarily encompasses the

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(quoting *The American Heritage Dictionary of the English Language* 1284 (1978)). The law review article Promega cites discussing a similar definition criticizes reliance on that definition in statutory interpretation as "inherently ambiguous and vague." Michael J. Malaguti, *Substantial Confusion: The Use and Misuse of the Word "Substantial" in the Legal Profession*, 52 N.H. Bar J. 6, 10 (Autumn 2011). The "fuller and more explanatory" definitions of most dictionaries, reflecting the obvious conceptual differences between quantitative size and qualitative importance, provide far better guidance than the "unreliable, rather threadbare definition[]" Promega asks this Court to adopt. A. Scalia & B. Garner, *Reading Law: the Interpretation of Legal Texts* 416-17 (2012).

supply of all the *important* ones." Br. 24 (alteration in original); see *Lowe* v. *SEC*, 472 U.S. 181, 208 n.53 (1985) ("we must give effect to every word that Congress used in the statute").

The use of the same phrase in other statutes further confirms its quantitative meaning. Three other statutes use the phrase "all or a substantial portion," and Promega concedes that "all of the statutes contemplate some amount or quantity," not "qualitative importance." Br. 20-21. Numerous other federal statutes similarly use the phrase "substantial portion" in a quantitative sense. See, *e.g.*, 16 U.S.C. § 1539(b)(2)(B) ("persons who ... derived a substantial portion of their income from the lawful taking of any listed species"); 20 U.S.C. § 1087-2(q)(2)(A) ("a substantial portion of eligible borrowers in such State"); 33 U.S.C. § 1286(f)(1) ("a substantial portion of the funds allocated to a State").

By contrast, none of the statutes that Promega relies upon uses the phrase "all or a substantial portion," and only one even includes the phrase "substantial portion." Promega's examples therefore demonstrate nothing more than that the word "substantial" can sometimes have a qualitative meaning, depending upon the context—a point that no party has disputed.

Promega relies most heavily upon *Goulding* v. *United States*, 957 F.2d 1420 (7th Cir. 1992), deferring to the Commissioner of Internal Revenue's position that the phrase "a substantial portion of a return" in 26 U.S.C. § 7701(a)(36)(A) can encompass a single entry that is of sufficient value and length. 957 F.2d at 1425. As the United States points out, this example does not support Promega's interpreta-

tion because that statute refers to "a substantial portion of any return," not "a substantial portion of the entries in a return." U.S. Br. 14-15 (emphasis omitted). A single entry that represents the vast majority of the length and value of a return could logically be a "substantial portion" of that return, "but it would be odd to say that a person who prepares only a single tax entry, even if large and complex, prepares a 'substantial portion *of the entries* in a return.'" *Id.* at 15. Here, if § 271(f)(1) imposed liability for the supply of a "substantial portion *of an invention*," the meaning of the word "substantial" would be far more ambiguous. *Id.* at 8. But the phrase "a substantial portion *of the components* of a patented invention" demonstrates "that the provision's applicability should turn on a comparison between the number of components supplied and the total number of components, rather than on an assessment of the importance of an individual component to the invention as a whole." *Id.* at 8-9. The holdings of certain state courts that an extremely valuable asset can be "substantially all" of a corporation's assets, Br. 20, have no bearing here for similar reasons.

Promega also relies upon this Court's holding that the Copyright Act's reference to "the amount and substantiality of the portion used" requires an "evaluation of the qualitative nature of the taking." *Harper & Row Publishers, Inc.* v. *Nation Enters.*, 471 U.S. 539, 564-65 (1985). Again, however, the context and phrasing of that statute are quite different from § 271(f)(1). The use of the phrase "*amount and* substantiality" demonstrates that the word "substantiality" in the Copyright Act cannot refer to the amount that is copied; otherwise, the statute's separate reference to "amount" would be surplusage.

Finally, Promega points to the Ninth Circuit's qualitative interpretation of 16 U.S.C. § 1532(6), Br. 19, covering a species "in danger of extinction throughout all or a significant portion of its range." *Defenders of Wildlife* v. *Norton*, 258 F.3d 1136, 1137 (9th Cir. 2001). That statute, however, does not use the word "substantial" at all. Further, the Ninth Circuit's holding was not driven by a textual analysis, but rather by the perceived purposes of the statute, its legislative history, and the practical consequences of each interpretation. Indeed, the court concluded that the statutory text was "inherently ambiguous, as it appears to use language in a manner in some tension with ordinary usage." *Id.* at 1141. Here, § 271(f)(1)'s text, structure, and purposes, as well as the presumption against extraterritoriality, all demonstrate that the phrase "substantial portion" refers to the number, not the importance, of the components supplied.

2. Promega's interpretation of § 271(f)(1) also cannot be squared with its companion provision, § 271(f)(2). Paragraph (f)(2) demonstrates that Congress did not intend liability to turn upon an amorphous, multi-factor analysis of a component's "importance"; instead, Congress adopted the well-defined and familiar patent standard of whether a component "is especially made or especially adapted" for the invention, excluding liability for the supply of a single "commodity of commerce." This "carefully crafted limit on liability would be substantially undermined if the domestic supplier of a single 'staple article or commodity' could be held liable under paragraph (1)." U.S. Br. 9. Indeed, under Promega's interpretation, § 271(f)(1) would all but subsume § 271(f)(2): Promega points to no circumstances where a component that is "especially made or especially adapted"

for an invention under (f)(2) would not also meet its malleable standard for "importance" under (f)(1).

Paragraph (f)(1)'s consistent use of the plural "components," compared with paragraph (f)(2)'s consistent use of the singular "component," is another strong textual indication that (f)(1) requires the supply of more than one component. Promega argues that the plural phrase "such components" in (f)(1) refers to all components of the invention, not the components supplied from the U.S., because only the combination of all components would "infringe [the patent] if such combination occurred within the United States." Br. 24. But Promega concedes that (f)(2) "uses the term 'such component' to refer to the matter supplied from the United States" in parallel phrasing, Br. 26, requiring that "such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States," 35 U.S.C. § 271(f)(2). The parallel phrases in these two subsections cannot reasonably be given opposing meanings. See *Mohasco Corp.* v. *Silver*, 447 U.S. 807, 826 (1980). Rather, both paragraphs are plainly referring to the combination of "such component[s]" supplied from the U.S. with the *remainder of the components of the invention supplied abroad* to create the entirety of the invention. See U.S. Br. 20.

Promega also offers the canard that "reading 'such components' to refer exclusively to what is supplied from the United States could permit a defendant to avoid liability under § 271(f)(1) merely by combining the U.S.-supplied components together into a single component before shipping it abroad." Br. 25. But U.S.-supplied components combined before export would still constitute multiple components "of a pa-

tented invention," and would still be "uncombined ... in part," because they would not be combined with the remainder of the components of the invention. See U.S. Br. 20 n.6.

In short, the statutory text and structure demonstrate that "substantial portion" refers to the quantity, not the importance, of the components.

II. THE PRESUMPTION AGAINST EXTRATERRITORIALITY FORECLOSES PROMEGA'S INTERPRETATION OF SECTION 271(f)(1).

In addition, the presumption against extraterritoriality forecloses Promega's unduly expansive standard. Promega barely contests that its approach would harm U.S. trade and create tensions with foreign sovereigns. Among other things, the Federal Circuit's interpretation "is at best of doubtful legitimacy under" international trade agreements including GATT and TRIPS, Brief of Bundesverband der Deutschen Industrie E.V., et al. ("BDI Br.") 10, and conflicts with E.U. patent and competition law, *id.* at 11-17.

Promega argues that such impacts are irrelevant, because its interpretation would not reach "conduct in foreign countries." Br. 47-48 (emphasis omitted). But that assertion simply ignores that Promega is asking to recover patent damages based on overwhelmingly foreign conduct: combining one U.S.-sourced commodity component with many foreign-sourced components and making and selling the product in countries where there is no foreign patent

protection. U.S. Br. 11.[2] Promega's insistence that no "foreign conduct" is being regulated rings particularly hollow because Promega sought and was awarded damages under U.S. patent law for *worldwide* sales of kits manufactured in foreign countries. JA143-44; JA166; JA173-74. Promega insists that Life Technologies' "global sales are relevant only to the measure of damages." Br. 47. But an award of damages based on foreign sales constitutes a regulation of those foreign sales. See *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 324 (2008) (damages "liability award can be, indeed is designed to be, a potent method of governing conduct"). And the presumption against extraterritoriality applies when a litigant seeks "recovery for foreign injuries." *RJR Nabisco, Inc.* v. *European Cmty.*, 136 S. Ct. 2090, 2106-07 (2016) (plurality). Moreover, under the Federal Circuit's ruling that a company can "induce" itself to infringe, a foreign manufacturer that makes and sells products entirely abroad could also be held liable for "caus[ing] to be supplied in or from the United States" a single commodity component. 35 U.S.C. § 271(f)(1).

Deepsouth further demonstrates that the solitary U.S. action of supplying one commodity component does not make the presumption inapplicable: that case applied the presumption even though the domestic manufacturer supplied *all* of the components from the United States, and only the final assembly occurred abroad. *Deepsouth Packing Co.* v. *Laitram Corp.*, 406 U.S. 518, 531 (1972). Indeed, as far back

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[2] Promega's suggestion that § 271(f)(1) does not require that "the foreign recipient actually makes the patented invention abroad" is incorrect. Br. 44; *see Applera Corp.* v. *MJ Research Inc.*, 311 F. Supp. 2d 293, 301 n.1 (D. Conn. 2004).

as *Brown* v. *Duchesne*, 60 U.S. (19 How.) 183 (1857), the Court has applied the presumption to reject the application of U.S. patent law over products made and sold abroad.

Microsoft similarly held that "[a]ny doubt" that "conduct falls outside § 271(f)'s compass would be resolved by the presumption against extraterritoriality." 550 U.S. at 454. Promega attempts to distinguish *Microsoft* as involving "*foreign-made* copies of a master version of software," not a U.S.-supplied "component." Br. 15. But the question presented in that case was whether the master version of the software supplied from the U.S. "qualif[ied] as a component under § 271(f)." *Microsoft*, 550 U.S. at 447. The Court applied the presumption in interpreting the word "component," holding that it "tugs strongly against" the Federal Circuit's broad construction. *Id.* at 455. The Court should follow the same approach here, in construing the phrase "all or a substantial portion."

Finally, Promega argues that the presumption does not apply because the United States and Life Technologies' interpretation is "not demonstrably narrower" than its own. Br. 49-50. This is baffling given how Promega is advocating throwing every case to a jury to decide. Indeed, Promega criticizes Life Technologies' standard for its "certainty ... that fewer culpable actors will be liable for infringement." Br. 41. Under the quantitative interpretation, § 271(f)(1) requires the supply of "a large percentage closely approximating all" of the components. Pet. Br. 4; see U.S. Br. 8. Thus, "makers of minor components," Br. 50, will not face liability unless the totality of what they supply is close to all of the components. Promega, by contrast, would hold manufacturers lia-

ble if they supply a "considerable ... amount" of components, *or* if they supply at least one component that is "important" for any reason a jury deems appropriate. Br. 12, 33.

The facts of this case highlight the near limitless malleability of Promega's proposal. The only evidence of "substantiality" Promega or the Federal Circuit identifies is testimony that *Taq* polymerase is a "main" component, and is needed for the kit to operate. Br. 8-9; Pet. App. 34a. But the same witness identified three out of the five components as "main" components. JA160. And Promega's expert testified that the remaining components were also "important" and needed for the kits to function. JA139 (the "control DNA" is "important," and must be included to "make sure the test worked"); JA138 ("we need to have" the buffer solution "because the chemical reaction can't take place in just simply water"); *id.* (the primers "are absolutely critical to this whole procedure"); *id.* (the kits "need to have" nucleotide mix "to make new DNA"). Thus, under Promega's test, any one of the five components, in isolation, would constitute "all or a substantial portion of the components" and trigger liability for worldwide sales. See U.S. Br. 16.

Promega's anything-goes interpretation conflicts with the "legitimate sovereign interests of other nations," *Microsoft*, 550 U.S. at 455, and could lead to serious international tensions. See Pet. Br. 30-33; U.S. Br. 29-30. "Any doubt" about the scope of § 271(f)(1) should be resolved by applying the presumption and rejecting Promega's importance-based interpretation. *Microsoft*, 550 U.S. at 454.

III. PROMEGA'S INTERPRETATION IS CONTRARY TO THE PURPOSES OF THE STATUTE AND UNADMINISTRABLE.

1. Promega's interpretation should also be rejected because it is contrary to the purposes of the statute. Promega agrees that § 271(f)(1)'s primary purpose is to close the loophole made evident in *Deepsouth* and "prevent defendants from deliberately circumventing U.S. patent law." Br. 27; see *Microsoft*, 550 U.S. at 457-58. But Promega then inaccurately argues that the "circumvention" Congress had in mind was "shipping major components of patented inventions from the United States." Br. 27. Rather, Congress was "focus[ed] on conduct that closely resembles the evasive conduct in *Deepsouth* and can reasonably be viewed as the functional equivalent of illicitly manufacturing the patented invention in the United States for export." U.S. Br. 10. Supplying a single commodity component from the U.S. "bears little resemblance to effectively manufacturing the invention in the United States," and is not the type of conduct Congress intended to prohibit. *Id.*

Promega points out that an earlier, rejected draft of the bill "would have prohibited a party from supplying 'the material components of a patented invention,'" arguing that this language demonstrates "Congress's attention was on the importance—not the number—of the components supplied." Br. 28 (emphases omitted). But this Court "ordinarily will not assume that Congress intended to enact statutory language that it has earlier discarded in favor of other language." *Chickasaw Nation* v. *United States*, 534 U.S. 84, 93 (2001). The rejected version undermines Promega's view. Congress's reason for rejecting the "material component" standard is also illumi-

nating: it was concerned that this broad standard would "deter the sale of components which are staple articles suitable for substantial noninfringing use." *Patent Law Improvement Act: Hearing Before the Subcomm. on Patents, Copyrights, and Trademarks of the S. Comm. of the Judiciary*, 98th Cong. 26 (1984). Congress protected the free flow of staple articles by splitting § 271(f) into two paragraphs: (f)(2), which excludes commodity components entirely, and (f)(1), which limits liability to "all or a substantial portion of the components."

Promega spends several pages arguing that its interpretation will only reach "culpable" manufacturers, because the supplier must intend that its customer will combine components overseas in a manner that would infringe a U.S. patent if performed domestically. Br. 34-40. This focus on "intent" is a distraction. The question this case asks is not whether a domestic supplier knows that the foreign-sold product is protected by a U.S. patent. The question is *when* does a U.S. patent reach such foreign sales. Generally, a product protected only by a U.S. patent may freely be made and sold overseas. *Microsoft*, 550 U.S. at 441. There is nothing "culpable" or illegal about participating in such sales, even if the U.S.-based supplier knows that its customer's product would infringe if sold in the U.S. Promega's assumption that Congress wanted to broadly expose manufacturers to U.S. patent liability for foreign sales based only on this intent is incompatible with the presumption against extraterritoriality—as well as with the United States' treaty obligations. See 10, *supra*.

Noting that § 271(f)(1)'s inducement requirement was drawn from §271(b), Br. 30, Promega contends that Congress was concerned with intent rather than

"the number of components," *id.*, because "a domestic sale of a single, non-staple component may create liability ... for inducement under § 271(b)," Br. 31-32. But Congress did not simply extend the § 271(b) standard for inducement to foreign sales. Congress added the requirement that "all or a substantial portion of the components" of an invention be supplied from the U.S. And as the United States observes, paragraph (f)(2) "contains substantially the same intent element" as paragraph (f)(1). U.S. Br. 21. Paragraph (f)(2) requires both "knowing" of the patent and "intending that such component will be combined outside of the United States in a manner that would infringe the patent." 35 U.S.C. § 271(f)(2). The "active inducement" element of paragraph (f)(1) is no more stringent, "requir[ing] knowledge of the patent and an intent that the domestically supplied components be combined into the patented invention." Br. 35. Yet "Congress nevertheless limited Section 271(f)(2) to the supply from the United States of a component that is ... not a staple article." U.S. Br. 21. The fact that Congress "specifically declined to impose infringement liability under Section 271(f)(2) for exporting a single staple article, *even when* the supplier knows and intends that it will be used to manufacture a patented invention abroad," demonstrates that Congress did not consider the intent element alone as sufficient protection for commodity components. *Id.* at 21-22.[3]

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[3] Further, while Promega apparently assumes that the "inducement" requirements of § 271(b) and § 271(f)(1) are the same, the Federal Circuit held below that § 271(f)(1) requires only that the defendant "cause" the "combination" of components abroad. Pet. App. 24a-27a. Thus, the Federal Circuit's interpretation of

By virtually eliminating the "substantial portion" requirement, Promega's interpretation would also frustrate Congress's intent to promote U.S. manufacturing jobs. Promega contends that Congress "determined that domestic companies like Deepsouth were more likely to cease infringement than move production overseas." Br. 38. But this determination makes sense *only* under Life Technologies' and the United States' construction of the statute: if a domestic company is completing nearly all the steps of manufacturing the product in the U.S., then § 271(f)(1) will discourage it from moving final assembly offshore. Pet. Br. 37. By contrast, Promega's expansive interpretation will sweep in foreign sales whose only connection to the U.S. is the sourcing of a single commodity component. That approach will "creat[e] major obstacles to the routine inclusion of United States firms and facilities in multinational manufacturing and supply arrangements," forcing U.S. component manufacturers to relocate offshore. BDI Br. 3. This Court should not adopt an overbroad interpretation that will operate directly contrary to Congress's intent.

2. Promega also contends that the quantitative interpretation will be difficult to apply and lead to "absurd" results. Br. 40-43. But determining whether close to all of the components of an invention has been supplied from the U.S. will generally be a relatively simple matter. U.S. Br. 26.

By contrast, Promega's test is fundamentally unclear and unworkable. Promega lists a wide variety of factors it deems pertinent, including a component's

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the inducement requirement leaves unclear whether § 271(f)(1) even requires the defendant to have knowledge of the patent.

"novelty," its "cost and value," its "function," marketing materials, and the number of components, Br. 33-34. But Promega offers no guidance as to how these factors are to be weighed, or how many factors must be present to render a portion "substantial." *Compare* Br. 12 ("substantial" means "considerable in amount *and/or* importance) (emphasis added), *with* Br. 18-19 (substantiality "turns on *both* the number of components supplied *and* their qualitative importance and value"). Promega even proposes a catch-all at the end of its list of unranked factors—and "any other relevant evidence"—leaving domestic component suppliers with nothing but speculation about how a jury would evaluate its conduct. Potential worldwide liability would always involve a "fact-intensive, case-specific inquiry" by the jury. Br. 12. But pointing to the jury's role as the fact-finder is no excuse for failing to provide a legal standard that is "conceptually stable or administrable," U.S. Br. 24, against which allegedly infringing conduct can be measured.

Promega also erroneously contends that the quantitative interpretation "would lead to absurd and arbitrary results," Br. 40, because "a U.S. manufacturer may be held liable for supplying multiple identical fasteners that hold together the outer housing of a device, but not for supplying a single processor that is the heart of the invention." Br. 50. Both halves of this assertion are wrong. If the "single processor" is "the heart of the invention," then it would not be a "staple article or commodity of commerce," and the manufacturer would be liable under 35 U.S.C. § 271(f)(2).

It is also highly unlikely that minor fasteners alone would "closely approximat[e] all" of the components of

the invention under § 271(f)(1). Pet. Br. 4. Indeed, the fasteners would probably not even qualify as components. As the United States explains, "[t]he starting point for identifying 'components' is to examine the elements of the relevant patent claim to identify constituent parts." U.S. Br. 27 n.7. Any part that is "not covered by any element of the patent claim" is not a component of the invention. *Id.* Thus, a manufacturer "could not evade liability" by "omitting any screws, bolts or rivets that hold the assembled invention together"; even if a patent claimed trivial commodity fasteners as an element of the invention, it is very unlikely it would claim each fastener as a separate element. *Id.* at 28 n.7. Indeed, patent holders have a strong incentive not to include trivial commodity components in their claims, since doing so makes avoiding infringement easier for competitors. See, *e.g.*, *PC Connector Solutions LLC* v. *SmartDisk Corp.*, 406 F.3d 1359, 1364 (Fed. Cir. 2005) ("Literal infringement requires that the accused device embody every element of the claim.").

Promega's argument that the quantitative interpretation is arbitrary because it "would allow multiple suppliers to collude to supply all of the components of a patented invention for assembly abroad" is similarly fallacious. Br. 14. The statute imposes liability upon anyone who "supplies *or causes to be supplied* ... all or a substantial portion of the components." 35 U.S.C. § 271(f)(1). A supplier who "colluded" to supply all of the components from the U.S. would therefore be liable, even if he personally supplied "only one or two" components. Br. 40.

The interpretation advanced by Life Technologies and the United States would not lead to any "absurd"

or "arbitrary" results, and it is far more workable than Promega's vague and overbroad approach.

IV. THE DISTRICT COURT'S JUDGMENT AS A MATTER OF LAW UNDER SECTION 271(f)(1) SHOULD BE REINSTATED.

Finally, Promega takes issue with the United States' statement that this case "comes to the Court on the assumption[] that ... petitioners are entitled to judgment as a matter of law unless the domestic supply of *Taq* polymerase alone is sufficient to trigger liability under Section 271(f)(1)." U.S. Br. 27; see Br. 51. The United States is correct. Promega chose to take "an 'all or nothing' approach at trial," seeking damages for all worldwide sales of all kits, and making no attempt to demonstrate the origin of components or the damages suffered from specific kits. JA173-74. Following trial, Life Technologies moved for judgment as a matter of law, arguing that given Promega's trial strategy, there was insufficient evidence to support the verdict unless *all* of the foreign sales infringed under § 271(f)(1).[4] Promega chose not to respond to this argument, and the district court therefore correctly "concluded that plaintiff had conceded this issue." JA179-80; see Pet. App. 52a. Promega does not even acknowledge this waiver ruling, much less demonstrate that it was an abuse of

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[4] Promega contends that the Federal Circuit rejected this ruling, but the Federal Circuit's analysis concerned only kits made and sold in the United States that infringe under 35 U.S.C. § 271(a). Pet. App. 35a. The Federal Circuit reversed the district court's judgment as to the foreign sales based upon its erroneous interpretation of § 271(f)(1). If this Court reverses that erroneous interpretation, the district court's judgment as a matter of law as to § 271(f)(1) should be reinstated.

discretion. See *In re Kutrubis*, 550 F. App'x 306 (7th Cir. 2013).

Promega's assertion that Life Technologies "conceded that it could be held liable under § 271(f)(1) for the three Identifiler kits for which Life Technologies supplied at least two components from the United States" is likewise erroneous. Br. 9-10. Life Technologies did not concede that two components would constitute a "substantial portion" of the components of the Tautz patent. Rather, in light of Promega's "all or nothing" strategy, Life Technologies argued that it was entitled to judgment as a matter of law unless *all* kits infringed, and for most kits Promega presented no evidence as to any component except *Taq* polymerase. Pet. App. 57a ("assum[ing]" without reaching the issue "that two components are a substantial portion"); A6505 (pointing out that Promega had introduced evidence showing the geographic origin of the components for only "*one* kit," and did not show "which sales were relative to the one kit that they did offer evidence on"). In addition, Life Technologies' statements cannot be read as a concession concerning the Tautz patent at all, because the trial involved four additional patents with claimed components more limited to narrow sets of primers. Those patents were held invalid on appeal. Pet. App. 22a.

Life Technologies also did not concede that two or even "multiple" components of the Tautz patent were supplied from the U.S. for any kit. Br. 39 (emphasis omitted). Rather, Life Technologies stated that Promega "offered evidence" that "some primers are manufactured in Pleasanton, California" for certain kits, while specifically noting that "the majority of the primers" for those kits "are manufactured in the U.K." A2303; see JA155 (same); Pet. App. 51a (noting that Promega "adduced evidence" regarding two

components for some kits). The relevant "component[] of a patented invention," 35 U.S.C. § 271(f)(1), is a "vessel containing a *mixture* of primers constituting between 1 and 50 of said primer pairs" that is capable of "analyzing polymorphism in at least one locus in an DNA sample." JA127 (col. 16; ll. 43-46) (emphasis added). Because this "primer mix" was manufactured in the U.K., JA158, the claimed primer component was not supplied from the U.S. for any kit. See Pet. Br. 8-9.

Promega argues that the primer component requires only "a single primer pair, and Life Technologies admittedly supplied multiple primers from the United States." Br. 52 n.13. However, Promega did not offer evidence that any "primer *pair*" was supplied from the U.S., much less that the primers supplied were capable of "analyzing polymorphism in at least one locus in an DNA sample." JA127 (col. 16; ll. 43-44). The district court's judgment as a matter of law regarding § 271(f)(1) should be reinstated.

Finally, if this Court accepted Promega's argument that determining whether components constitute a "substantial portion" requires analyzing "*both* the relative importance and the quantity of the components supplied," the Federal Circuit's ruling must still be reversed. Br. 51. The Federal Circuit did not weigh the "relative importance" of the *Taq* polymerase against the fact that only one out of the five components had been supplied. Nor did the Federal Circuit weigh the vast majority of the factors that Promega now asserts are relevant. Br. 33. In fact, the evidence at trial makes clear that *Taq* polymerase was not "novel[] within the industry," *id.*; Promega points out that a well-known journal "named Taq polymerase the first 'Molecule of the Year'" *in 1989*—years before the patent was issued.

Br. 5; see JA120 (col. 1; ll. 8-12). Further, there was no evidence that *Taq* polymerase is valuable or was featured in materials promoting the invention. See https://www.neb.com/products/m0273-taq-dna-polymerase-with-standard-taq-buffer (*Taq* polymerase sold at six cents per unit). Even if this Court adopts an importance-based balancing test—which it should not—the judgment below must be reversed.

CONCLUSION

For the foregoing reasons and those set forth in the opening brief, this Court should reverse the decision of the Federal Circuit.

Respectfully submitted,

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